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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/320,713	05/27/99	EBNER R	PF470

EXAMINER

HM22/0808

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ART UNIT	PAPER NUMBER
1647	6

DATE MAILED: 08/08/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-49 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-49 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

* U S GPO: 1996-409-290/40029

Part III: Detailed Office Action

Notice: Effective June 18, 2000, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit **1647**.

Restriction Requirement:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 4, 5, 7, 8, 10, 11, 13-17, 19, 20, 22, 23, 30, 31, 33, 34, 41 and 42, drawn to nucleic acids encoding IL-21, vectors, host cells and recombinant expression, classified in class 435, subclass 69.1.

II. Claims 3, 6, 9, 12, 18, 21, 24, 32, 35 and 43, drawn to nucleic acids encoding IL-22, vectors, host cells and recombinant expression, classified in class 435, subclass 69.1.

III. Claims 25, 26, 28, 36, 47 and 48, drawn to IL-21, classified in class 530, subclass 350.

IV. Claims 27 and 49, drawn to IL-22, classified in class 530, subclass 350.

V. Claim 29, drawn to anti-IL-21 antibodies, classified in class 530, subclass 387.9.

VI. Claim 37, drawn to a method of treatment using IL-21, classified in class 514, subclass 2.

VII. Claim 38, drawn to diagnostic method via mutation detection (nucleic acid), classified in class 435, subclass 6.

VIII. Claim 39, drawn to an assay for IL-21, classified in class 435, subclass 7.1.

IX. Claim 40, drawn to an assay for IL-21 'binding partners', classified in class 436, subclass 501.

X. Claims 44-45, drawn to an assay for IL-21 activity , classified in class 435, subclass 6.

XI. Claims 46 , drawn to an assay for IL-22 activity, classified in class 435, subclass 6.

The inventions are distinct, each from the other because:

Each of Inventions I, III, and V-X are drawn broadly to aspects of IL-21, while each of inventions II, IV and XI are drawn broadly to aspects of IL-22. As IL-21 and IL-22 are substantively different proteins, with distinct structural and functional properties, and as the searches for the two are non-overlapping, each of inventions I, III, and V-X is separate and distinct from each of inventions II, IV and XI.

Among Inventions I, III, and V-X:

The nucleic acids of Invention I are related to the protein of Invention III by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The nucleic acids, vectors and host cells of invention I are separate and distinct from the antibodies of Invention V wherein the various products are physically and functionally distinct, and are capable of separate manufacture and use.

The methods of invention I are separate and distinct from the products of invention V wherein the product may neither be made by nor used in the methods.

The methods of Invention I are separate and distinct from the various methods of Invention VI-X wherein the respective method steps are functionally distinct, and achieve different ends.

The products of Invention I are separate and distinct from the various methods of Inventions VI-IX wherein the products are neither made by nor used in the methods.

Inventions I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed

can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids be used as hybridization probes, and the transformed cells may be used for recombinant production of protein to be purified, which may not require production of soluble protein to be isolated from supernatant.

The proteins of Invention III are related to the antibodies of Invention V by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural receptor of the protein, or in assays for the identification of agonists or antagonists of the protein.

The proteins of Invention III are related to the methods of Inventions VI, VIII and IX as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins be used in any of the three patentably distinct processes, or alternatively as an antigen for the production of antibodies such as those of Invention V.

The proteins of Invention III are separate and distinct from Invention VII wherein the protein is neither made by nor used in the method.

The proteins of Invention III are separate and distinct from Invention X wherein although the protein is made in the course of performing the assay of Invention X, the protein can be made by other means, such as purification from the natural source, or expression in a non-secreting system. Accordingly, the Inventions are distinct and capable of supporting separate patents.

The antibodies of Invention V are separate and distinct from the various methods of Inventions VI, VII, and X, wherein the antibodies are neither made by nor used in the methods.

The antibodies of Invention V are related to the methods of Inventions VIII and IX as

product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins be used in any of the two patentably distinct processes, or alternatively as reagent for the purification of the protein of Invention III (e.g. on a column) or as a pharmaceutical in their own right. Accordingly, restriction is proper.

The various methods of Inventions VI-X constitute distinct inventions because most of the various methods involve the use of different active agents, and have different process steps and results and therefore constitute distinct and unrelated methods. Of the methods which share active agents, Inventions VI, VIII and IX are distinct because they involve different process steps, and divergent searches. Similarly, although Inventions VII and X both use nucleic acids, the detection of mutation as claimed in Invention VII involves substantively different process steps than the assay of Invention X, which is ultimately an assay for biological activity of the protein encoded by the non-mutated nucleic acid. In all these cases, it would present an undue burden on the Examiner to search the different inventions, as the search for obviousness of each of the inventions is largely non-overlapping of that of the other inventions.

Among Inventions II, IV and XI:

The nucleic acids of Invention II are related to the protein of Invention IV by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Inventions II and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids be used as hybridization probes, and the transformed cells may be used for recombinant production of protein to be purified, which may not require production of soluble protein to be isolated from supernatant.

The proteins of Invention IV are separate and distinct from Invention XI wherein although the protein is made in the course of performing the assay of Invention XI, the protein can be made by other means, such as purification from the natural source, or expression in a non-secreting system. Accordingly, the Inventions are distinct and capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 37 C.F.R. § 1.48(b) and by the fee required under 37 37 C.F.R. § 1.17(i).

Advisory Information:

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 8:00 A.M. to 4:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.

Lorraine Spector, Ph.D.
Primary Examiner

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